



1636

1636

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**In re Application of:**

Khan et al.

**Serial No.:** 10/028,075

**Filed:** December 21, 2001

**For:** GENE REGULATOR

**Confirmation No.:** 1102

**Examiner:** J. Dunston

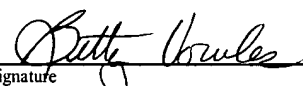
**Group Art Unit:** 1636

**Attorney Docket No.:** 2183-5223US

CERTIFICATE OF MAILING

I hereby certify that this correspondence along with any attachments referred to or identified as being attached or enclosed is being deposited with the United States Postal Service as First Class Mail on the date of deposit shown below with sufficient postage and in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

December 6 2006  
Date

  
Signature

Betty Vowles  
Name (Type/Print)

COMMUNICATION

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

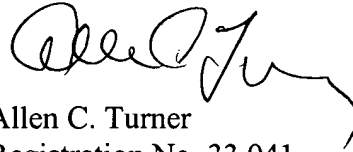
Sir:

A recent review of the Information Disclosure Statements in the referenced application indicates that some PTO/SB/08 forms have not been initialed and returned. For the convenience of the Examiner, applicants attach Information Disclosure Statements that have not been initialed and returned. Applicants note that some of the references have recently been submitted and, therefore, acknowledge that review of these documents is probably still in progress. However, some references were submitted before the current Examiner had custody of the case. They apparently should have been reviewed and returned to applicant by a prior Examiner.

Serial No. 10/028,075

Applicants request an initialed copy of the attached Information Disclosure Statements.

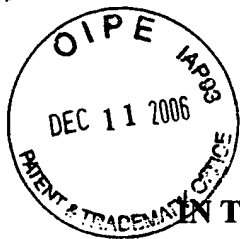
Respectfully submitted,



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Date: December 7, 2006  
ACT/bv

Enclosures: Information Disclosure Statements Mailed:  
February 4, 2002  
October 15, 2002  
January 7, 2004  
May 11, 2004  
June 30, 2006  
September 25, 2006  
November 9, 2006



**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**In re Application of:**

Khan et al.

**Serial No.:** 10/028,075

**Filed:** December 21, 2001

**For:** GENE REFULATOR

**Examiner:** To be assigned

**Group Art Unit:** 1632

**Attorney Docket No.:** 2183-5223US

**NOTICE OF EXPRESS MAILING**

Express Mail Mailing Label Number: EV175437512US

Date of Deposit with USPS: October 15 2002

Person making Deposit: Orlena Howell

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 or PTO/SB/08 be considered by the Examiner and made of record. Copies of the listed documents are enclosed pursuant to 37 C.F.R. § 1.98(a).

In accordance with 37 C.F.R. § 1.97(g) and (h), filing of this Information Disclosure Statement is not to be construed as a representation that a search has been made or an admission that the information cited herein is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b). Further, no representation is made by Applicants herein that no other possible material information as defined in 37 C.F.R. § 1.56(b) exists.

Foreign Patent Documents

<u>Document No.</u>	<u>Publication Date</u>	<u>Patentee</u>
WO 99/59617	11-25-1999	Erasmus Universiteit
WO 97/49721	12-31-1997	University of Maryland

Other Documents

PCT International Search Report, PCT/NL01/00259, dated December 18, 2001, 3 pages.

PCT International Preliminary Examination Report, PCT/NL99/00313, dated July 21, 2000, 6 pages.

PCT International Search Report, PCT/EP99/00313, dated November 29, 1999, 3 pages.

Lang et al., "Induction of apoptosis in Kaposi's sarcoma spindle cell cultures by the subunits of human chorionic gonadotropin", AIDS 1997, Vol. 11, No. 11, pp.1333-1340.

Iskandar et al., "Effects of a urinary factor from women in early pregnancy on HIV-1. SIV and associated disease", Nature Medicine, April 1998, Vol. 4, No. 4, pp. 428-434.

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56 & 1.175, applicant hereby identifies the following listed copending applications naming the same inventor(s):

Attorney Docket No.: 2183-4618US  
Serial No.: 09/716,777  
Filing Date: 11/20/2000  
For: IMMUNOREGULATOR

Attorney Docket No.: 2183-4799US  
Serial No.: 09/821,380  
Filing Date: 3/29/2001  
For: IMMUNOREGULATOR

Attorney Docket No.: 2183-5223US  
Serial No.: 10/028,075  
Filing Date: 12/21/2001  
For: GENE REGULATOR

Serial No.: 10/028,075

Attorney Docket No.: 2183-5526US  
Serial No.: To be assigned  
Filing Date: 9/30/2002  
For: IMMUNOREGULATOR

This Information Disclosure Statement is believed to be filed before the mailing date of the first Office Action on the merits, and no certification pursuant to 37 C.F.R. § 1.97(c) or a fee pursuant to 37 C.F.R. § 1.17(p) is required.

Respectfully submitted,



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Date: October 11, 2002  
BLC/bv  
Enclosures: Form PTO-1449 or PTO/SB/08  
Cited Documents  
Document in ProLaw



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Khan et al.

Serial No.: 10/028,075

Filed: December 21, 2001

For: GENE REGULATOR

Examiner: To be assigned

Group Art Unit: To be assigned

Attorney Docket No.: 2183-5223US

CERTIFICATE OF MAILING

I hereby certify that this correspondence along with any attachments referred to or identified as being attached or enclosed is being deposited with the United States Postal Service as First Class Mail (under 37 C.F.R. § 1.8(a)) on the date of deposit shown below with sufficient postage and in an envelope addressed to the Commissioner for Patents, Washington, D.C. 20231.

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Lynette Eliason  
Signature of registered practitioner or other person having reasonable basis to expect mailing to occur on date of deposit shown pursuant to 37 C.F.R. § 1.8(a)(1)(ii)

Lynette Eliason  
Typed/printed name of person whose signature is contained above

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
Washington, D.C. 20231

Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 or PTO/SB/08A be considered by the Examiner and made of record. Copies of the listed documents are enclosed pursuant to 37 C.F.R. § 1.98(a).

In accordance with 37 C.F.R. § 1.97(g) and (h), filing of this Information Disclosure Statement is not to be construed as a representation that a search has been made or an admission that the information cited herein is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b). Further, no representation is made by Applicants herein that no other possible material information as defined in 37 C.F.R. § 1.56(b) exists.

DOCUMENTS

U.S. Patent Documents

<u>U.S. Patent No.</u>	<u>Inventor</u>	<u>Issue Date</u>
6,319,504	Gallo et al.	11-20-2001

Other Documents

CONNELLY et al., Biphasic Regulation of NF-kB Activity Underlies the Pro- and Anti-Inflammatory Actions of Nitric Oxide, The Journal of Immunology, 2001, pp. 3873-81, 166, The American Association of Immunologists, USA.

FRIEDLANDER, Tackling anthrax, Nature, November 8, 2001, pp. 160-61, Vol. 414.

MEDZHITOV, Toll-like Receptors and Innate Immunity, Nature Reviews/Immunology, November 2001, pp. 135-45, Vol. 1.

Applicants offer to supply any explanation or discussion of the documents that the Examiner feels is necessary or desirable and which is requested.

This Information Disclosure Statement is filed within three (3) months of the filing date of the above-identified application, and no certification pursuant to 37 C.F.R. § 1.97(c) or a fee pursuant to 37 C.F.R. § 1.17(p) is required.

Respectfully submitted,



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Date: February 4, 2002

ACT/bv

Enclosures: Form PTO-1449 or PTO/SB/08A  
Copy of documents cited



**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**In re Application of:**

Khan et al.

**Serial No.:** 10/028,075

**Filed:** December 21, 2001

**For:** GENE REGULATOR

**Confirmation No.:** 1102

**Examiner:** T. McKelvey

**Group Art Unit:** 1636

**Attorney Docket No.:** 2183-5223US

**CERTIFICATE OF MAILING**

I hereby certify that this correspondence along with any attachments referred to or identified as being attached or enclosed is being deposited with the United States Postal Service as First Class Mail on the date of deposit shown below with sufficient postage and in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

May 11, 2004  
Date

*Betty Vowles*  
Signature

Betty Vowles  
Name (Type/Print)

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Supplemental Information Disclosure Statement be entered and the documents listed on attached Form PTO/SB/08 be considered by the Examiner and made of record. Copies of the listed documents are enclosed pursuant to 37 C.F.R. § 1.98(a).

In accordance with 37 C.F.R. § 1.97(g) and (h), filing of this Supplemental Information Disclosure Statement is not to be construed as a representation that a search has been made or an admission that the information cited herein is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b). Further, no representation is made by Applicants herein that no other possible material information as defined in 37 C.F.R. § 1.56 (b) exists.



Serial No.: 10/028,075

U.S. Patent Documents

<u>U.S. Patent No.</u>	<u>Publication Date</u>	<u>Patentee</u>
US - 5,380,668	01-10-1995	Herron
US - 2003/0186244 A1	10-02-2003	Margus et al.
US - 2003/0113733 A1	06-19-2003	Khan et al.
US - 2003/0119720 A1	06-26-2003	Khan et al.
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US - 2003/0220261 A1	11-27-2003	Khan et al.
US - 2003/0224995 A1	12-04-2003	Khan et al.
US - 2004/0013661 A1	01-22-2004	Wensvoort et al.

Foreign Patent Documents

<u>Document No.</u>	<u>Publication Date</u>	<u>Patentee</u>
WO 03/029292 A2	04-10-2003	Erasmus Universiteit Rotterdam

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, Applicants hereby identify the following listed copending applications naming a common inventor(s):

Attorney Docket No.: 3077-6084US  
Serial No.: 10/753,510  
Filing Date: 1/7/2004  
Title: IMMUNOREGULATORY COMPOSITIONS

Serial No.: 10/028,075

Attorney Docket No.: 3077-6420US  
Serial No.: 10/821,256  
Filing Date: 4/8/2004  
Title: COMPOSITIONS CAPABLE OF REDUCING ELEVATED  
BLOOD UREA CONCENTRATION

Attorney Docket No.: 3077-6384US  
Serial No.: 10/821,240  
Filing Date: 4/8/2004  
Title: METHODS AND USES FOR PROTEIN BREAKDOWN  
PRODUCTS

This Supplemental Information Disclosure Statement is filed after the mailing date of the first Office Action on the merits.

The fee pursuant to 37 C.F.R. § 1.17(p) is enclosed.

Respectfully submitted,



Allen C. Turner  
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Date: May 7, 2004  
ACT/bv

Enclosures: Form PTO/SB/08  
Copy of documents cited  
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**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**In re Application of:**

Khan et al.

**Serial No.:** 10/028,075

**Filed:** December 21, 2001

**For:** GENE REGULATOR

**Confirmation No.:** 1102

**Examiner:** T. McKelvey

**Group Art Unit:** 1636

**Attorney Docket No.:** 2183-5223US

**NOTICE OF EXPRESS MAILING**

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Date of Deposit with USPS: June 30, 2006

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**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

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In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Supplemental Information Disclosure Statement be entered and the documents listed on attached Form PTO/SB/08 be considered by the Examiner and made of record. Copies of the listed documents are enclosed pursuant to 37 C.F.R. § 1.98(a).

Serial No.: 10/028,075

U.S. Patent Documents

<u>U.S. Patent No.</u>	<u>Publication Date</u>	<u>Patentee</u>
US - 6,727,227	04-27-2004	Khavinson

Foreign Patent Documents

<u>Document No.</u>	<u>Publication Date</u>	<u>Patentee</u>
WO 01/29067	04-26-2001	Obschestvo S Ogranichennoi Otvetstvennostiju "Klinika Instituta Bioregulyatsii I Gerontologii"

Other Documents

KACHRA et al., "Low Molecular Weight Components but Not Dimeric HCG Inhibit Growth and Down-Regulate AP-1 Transcription Factor in Kaposi's Sarcoma Cells," Endocrinology, 1997, pp. 4038-4041, vol. 138, no. 9.

KHAVINSON et al., "Mechanisms Underlying Geroprotective Effects of Peptides," Bulletin of Experimental Biology and Medicine, January 2002, pp. 1-5, Vol. 133, No. 1.

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KHAVINSON et al, Gerontological Aspects of Genome Peptide Regulation, 2005, S. Karger AG, Basel, Switzerland.

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, Applicants hereby identify the following listed copending applications naming a common inventor(s):

Attorney Docket No.: 3077-6084US  
Serial No.: 10/753,510  
Filed: 1/7/2004  
Title: IMMUNOREGULATORY COMPOSITIONS

Attorney Docket No.: 2183-6400US  
Serial No.: 10/817,756  
Filed: 4/2/2004  
Title: GENE REGULATORY PEPTIDES

Attorney Docket No.: 3077-6384US  
Serial No.: 10/821,240  
Filed: 4/8/2004  
Title: METHODS AND USES FOR PROTEIN BREAKDOWN PRODUCTS

Attorney Docket No.: 3077-6420US  
Serial No.: 10/821,256  
Filed: 4/8/2004  
Title: COMPOSITIONS CAPABLE OF REDUCING ELEVATED BLOOD UREA CONCENTRATION

**Serial No.: 10/028,075**

**Attorney Docket No.: 2183-4799.1US**  
**Serial No.: 11/037,972**  
**Filed: 1/18/2005**  
**Title: IMMUNOREGULATOR**

**Attorney Docket No.: 3077-6418US**  
**Serial No.: 11/243,438**  
**Filed: 10/4/2005**  
**Title: COMPOSITIONS FOR MUCOSAL AND ORAL  
ADMINISTRATION COMPRISING HCG FRAGMENTS**

**Attorney Docket No.: 3077-6420.2US**  
**Serial No.: 11/249,541**  
**Filed: 10/13/2005**  
**Title: COMPOSITIONS CAPABLE OF REDUCING ELEVATED BLOOD  
UREA CONCENTRATION**

**Attorney Docket No.: 3077-7568US**  
**Serial No.: 11/286,571**  
**Filed: 11/23/2005**  
**Title: COMPOUNDS OF THERAPEUTIC VALUE IN THE TREATMENT  
OF MULTIPLE SCLEROSIS AND OTHER DISEASES WHEREIN  
FOAM CELLS ARE INVOLVED IN THE DISEASE ETIOLOGY**

**Attorney Docket No.: 3077-7643US**  
**Serial No.: 11/346,450**  
**Filed: 2/2/2006**  
**Title: COMPOSITIONS CAPABLE OF REDUCING ELEVATED BLOOD  
UREA CONCENTRATION**

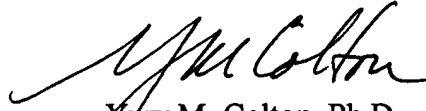
**Attorney Docket No.: 3077-7568.1US**  
**Serial No.: 11/346,761**  
**Filed: 2/3/2006**  
**Title: COMPOUNDS OF THERAPEUTIC VALUE IN THE TREATMENT  
OF MULTIPLE SCLEROSIS AND OTHER DISEASES WHEREIN  
FOAM CELLS ARE INVOLVED IN THE DISEASE ETIOLOGY**

**Attorney Docket No.: 2183-7849US**  
**Serial No.: 11/446,458**  
**Filed: 6/2/2006**  
**Title: METHOD TO DIAGNOSE OR SCREEN FOR INFLAMMATORY  
DISEASES**

Serial No.: 10/028,075

This Supplemental Information Disclosure Statement is believed to be filed before the mailing date of the first Office Action on the merits subsequent to the filing of an RCE in the above-identified application.

Respectfully submitted,



Yury M. Colton, Ph.D.  
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Telephone: 801-532-1922

Date: June 30, 2006  
ACT/alb

Enclosures: Form PTO/SB/08  
Copy of documents cited



**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**In re Application of:** Khan et al.

**Serial No.:** 10/028,075

**Filed:** December 21, 2001

**For:** GENE REGULATOR

**Confirmation No.:** 1102

**Examiner:** J. Dunston

**Group Art Unit:** 1636

**Attorney Docket No.:** 2183-5223US

**CERTIFICATE OF MAILING**

I hereby certify that this correspondence along with any attachments referred to or identified as being attached or enclosed is being deposited with the United States Postal Service as First Class Mail on the date of deposit shown below with sufficient postage and in an envelope addressed to the Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

September 25, 2006  
Date

  
Signature

Aubry Blackburn  
Name (Type/Print)

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Supplemental Information Disclosure Statement be entered and the documents listed on attached Form PTO/SB/08 be considered by the Examiner and made of record. Copies of any cited foreign patents, publications, or pending unpublished U.S. applications are enclosed pursuant to 37 C.F.R. § 1.98(a)(2).

**U.S. Patent Documents**

<u>U.S. Patent No.</u>	<u>Publication Date</u>	<u>Patentee</u>
US - 2003/0148955	08-2003	Pluenneke
US - 4,427,660	01-1984	Schiffman et al.
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Serial No.: 10/028,075

US - 4,753,965	06-1988	Stemerick et al.
US - 5,002,961	03-1991	Dage et al.
US - 5,223,397	06-1993	Pouletty
US - 5,801,193	09-1998	Ojo-Amaize et al.
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US - 6,310,041	10-2001	Haddox et al.
US - 6,630,138	10-2003	Gerlitz et al.
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Foreign Patent Documents

<u>Document No.</u>	<u>Publication Date</u>	<u>Patentee</u>
WO 98/34631 A1	08-1998	Thomas Jefferson University
WO 2001/83554 A2	11-2001	Praecis Pharmaceuticals Incorporated et al.

Other Documents

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**Serial No.: 10/028,075**

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TRAYSTMAN, R., "Animal Models of Focal and Global Cerebral Ischemia," ILAR Journal, 2003, pp. 85-95, Vol. 44, No. 2.

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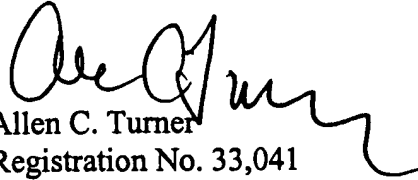
In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, Applicants hereby identify the following listed copending applications naming a common inventor(s):

Attorney Docket No.: 2183-7350.1US  
Serial No.: 11/481,423  
Filed: 7/5/2006  
Title: TREATMENT FOR TUMORS

This Supplemental Information Disclosure Statement is believed to be filed before the mailing date of the first Office Action on the merits subsequent to the filing of an RCE in the above-identified application.

Serial No.: 10/028,075

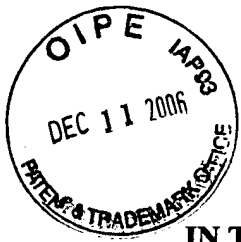
Respectfully submitted,



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Telephone: 801-532-1922

Date: September 25, 2006  
ACT/alb

Enclosures: Form PTO/SB/08  
Cited Non-U.S. Patent Documents  
Document in ProLaw



**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**In re Application of:**

Khan et. al.

**Serial No.:** 10/028,075

**Filed:** December 21, 2001

**For:** GENE REGULATOR

**Examiner:** T. McKelvey

**Group Art Unit:** 1632

**Attorney Docket No.:** 2183-5223US

**CERTIFICATE OF MAILING**

I hereby certify that this correspondence along with any attachments referred to or identified as being attached or enclosed is being deposited with the United States Postal Service as First Class Mail on the date of deposit shown below with sufficient postage and in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

January 7, 2004  
Date

  
Signature

Betty Vowles  
Name (Type/Print)

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 or PTO/SB/08 be considered by the Examiner and made of record. Copies of the listed documents are enclosed pursuant to 37 C.F.R. § 1.98(a).

In accordance with 37 C.F.R. § 1.97(g) and (h), filing of this Information Disclosure Statement is not to be construed as a representation that a search has been made or an admission that the information cited herein is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b). Further, no representation is made by Applicants herein that no other possible material information as defined in 37 C.F.R. § 1.56(b) exists.

U.S. Patent Documents

<u>U.S. Patent No.</u>	<u>Publication Date</u>	<u>Patentee</u>
US- 4,977,244	12-11-1990	Muchmore et al.
US- 5,677,275	10-14-1997	Lunardi-Iskandar et al.
US- 5,877,148	03-02-1999	Lunardi-Iskandar et al.
US- 5,958,413	09-28-1999	Anagnostopulos et al.
US- 5,997,871	12-07-1999	Gallo et al.
US- 6,319,504 B1	11-20-2001	Gallo et al.
US- 2003/0049273 A1	03-13-2003	Gallo et al.
US- 6,583,109 B1	06-24-2003	Gallo et al.
US- 6,596,688 B1	07-22-2003	Gallo et al.
US- 6,620,416 B1	09-16-2003	Gallo et al.
US- 2002/0064501	05-30-2002	Khan et al.
US- 2002/0041871	04-11-2002	Brudnak
US-5,851,997	12-22-1998	Harris
US- 6,489,296	12-03-2002	Grinnell et al.

Foreign Patent Documents

<u>Document No.</u>	<u>Publication Date</u>	<u>Patentee</u>
EP 1 300 418	04-09-2003	Erasmus Universiteit Rotterdam
WO 98/35691	08-20-1998	Proscript, Inc.
WO 02/085117	10-31-2002	Eisai Co., Ltd.
DE 3715662	11-19-1987	The Wellcome Foundation Ltd.
DE 19953339	05-17-2001	Goldham Pharma GmbH
96/04008	02-15-1996	Government of the United States
97/49373	12-31-1997	University of Maryland

Serial No.: 10/028,075

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12-31-1997

Biotechnology Institute

University of Maryland

Biotechnology Institute

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Biotechnology Institute

97/49432

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MUCHMORE et al., Immunoregulatory Properties of Fractions from Human Pregnancy Urine: Evidence that Human Chorionic Gonadotropin is not Responsible, *The Journal of Immunology*, March 1997, pp. 881-86, Vol. 118, No. 3.

MUCHMORE et al., Purification and Characterization of a Mannose-Containing Disaccharide Obtained from Human Pregnancy Urine, *Journal of Experimental Medicine*, December 1984, pp. 1672-85, Volume 160.

**Serial No.: 10/028,075**

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56 & 1.175, Applicants offer hereby identifies the following listed copending applications naming the same inventor(s):

Attorney Docket No.: 3077-5951US  
Serial No.: 10/409,027  
Filing Date: 4/8/2003  
Title: TREATMENT OF TRANSPLANT SURVIVAL

Attorney Docket No.: 3077-5952US  
Serial No.: 10/409,032  
Filing Date: 4/8/2003  
Title: TREATMENT OF TRAUMA

Attorney Docket No.: 3077-5953US  
Serial No.: 10/409,630  
Filing Date: 4/8/2003  
Title: TREATMENT OF MULTIPLE SCLEROSIS

Attorney Docket No.: 3077-5957US  
Serial No.: 10/409,642  
Filing Date: 4/8/2003  
Title: TREATMENT OF ISCHEMIC EVENTS

Attorney Docket No.: 3077-5958US  
Serial No.: 10/409,654  
Filing Date: 4/8/2003  
Title: TREATMENT OF NEUROLOGICAL DISORDERS

Attorney Docket No.: 3077-5960US  
Serial No.: 10/409,657  
Filing Date: 4/8/2003  
Title: STRATIFICATION

Attorney Docket No.: 3077-5956US  
Serial No.: 10/409,659  
Filing Date: 4/8/2003  
Title: PEPTIDE COMPOSITIONS



Serial No.: 10/028,075

Attorney Docket No.: 3077-5959US  
Serial No.: 10/409,668  
Filing Date: 4/8/2003  
Title: ADMINISTRATION OF GENE-REGULATORY PEPTIDES

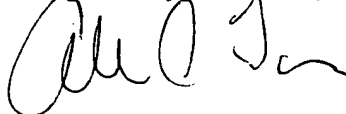
Attorney Docket No.: 3077-5955US  
Serial No.: 10/409,671  
Filing Date: 4/8/2003  
Title: TREATMENT OF IATROGENIC DISEASE

Attorney Docket No.: 3077-5954US  
Serial No.: 10/409,694  
Filing Date: 4/8/2003  
Title: TREATMENT OF BURNS

Attorney Docket No.: 3077-4618.1US  
Serial No.: 10/678,995  
Filing Date: 10/3/2003  
Title: IMMUNOREGULATOR

This Supplemental Information Disclosure Statement is filed before the mailing date of the first Office Action on the merits; however, should a fee be required, please debit Deposit Account No. 20-1469.

Respectfully submitted,



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Date: January 7, 2004  
ACT/bv  
Enclosures: Form PTO/SB/08

Document in ProLaw



**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**In re Application of:**

**Khan et al.**

**Serial No.: 10/028,075**

**Filed: December 21, 2001**

**For: GENE REGULATOR**

**Confirmation No.: 1102**

**Examiner: J. Dunston**

**Group Art Unit: 1636**

**Attorney Docket No.: 2183-5223US**

**NOTICE OF EXPRESS MAILING**

Express Mail Mailing Label Number: EV826306775US

Date of Deposit with USPS: November 9, 2006

Person making Deposit: Brett Hooke

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Supplemental Information Disclosure Statement be entered and the documents listed on attached Form PTO/SB/08 be considered by the Examiner and made of record. Copies of any cited foreign patents, publications, or pending unpublished U.S. applications are enclosed pursuant to 37 C.F.R. § 1.98(a)(2).

U.S. Patent Documents

<u>U.S. Patent No.</u>	<u>Publication Date</u>	<u>Patentee</u>
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US - 5,994,126	11-1999	Steinman et al.
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US - 2004/0208885 A1	10-2004	Khan et al.
US - 6,844,315	01-2005	Khan et al.
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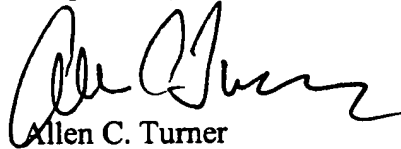
Other Documents

- CUI et al., Am. J. Physiol. Integr. Comp. Physiol., 2004, pp. R699-R709, Vol. 286.
- DWINNELL et al., Atlas of Diseases of the Kidney, Blackwell Sciences, 1999, pp. 12.1-12.12, Ch. 12.
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- NGO et al., The protein folding problem and tertiary structure prediction, 1994, pp. 492-94.
- PELLIZZARI et al., FEBS Letters, 1999, pp. 199-204, Vol. 462.

This Supplemental Information Disclosure Statement is believed to be filed before the mailing date of a first Office Action on the merits; therefore, no fee is due.

Serial No.: 10/028,075

Respectfully submitted,



Allen C. Turner

Registration No. 33,041

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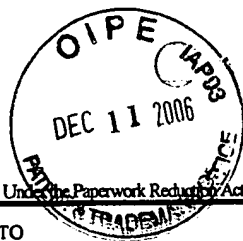
Date: November 1, 2006

ACT/bv

Enclosures: Form PTO/SB/08

Cited Non-U.S. Patent Documents

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PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 3

**Complete if Known**

Application Number	10/028,075
Filing Date	December 21, 2001
First Named Inventor	Khan et al.
Group Art Unit	1636
Examiner Name	J. Dunston
Attorney Docket Number	2183-5223US

**U.S. PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
		US-2003/0148955	08-2003	Plueneke	
		US- 4,427,660	01-1984	Schiffman et al.	
		US- 4,571,338	02-1986	Houck et al.	
		US- 4,753,965	06-1988	Stermick et al.	
		US- 5,002,961	03-1991	Dage et al.	
		US- 5,223,397	06-1993	Pouletty	
		US- 5,801,193	09-1998	Ojo-Amaize et al.	
		US- 5,942,494	08-1999	Ginsberg et al.	
		US- 5,972,824	10-1999	Keep et al.	
		US- 6,051,596	04-2000	Badger	
		US- 6,075,150	06-2000	Wang et al.	
		US- 6,235,281	05-2001	Stenzel et al.	
		US- 6,310,041	10-2001	Haddox et al.	
		US- 6,630,138	10-2003	Gerlitz et al.	
		US- 6,831,057	12-2004	Baldwin et al.	
		US-			
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**FOREIGN PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
		WO 98/34631 A1	08-1998	Thomas Jefferson University		
		WO 2001/83554 A2	11-2001	Praecis Pharmaceuticals Incorporated et al.		

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

2

of

3

**Complete if Known**

Application Number	10/028,075
Filing Date	December 21, 2001
First Named Inventor	Khan et al.
Group Art Unit	1636
Examiner Name	J. Dunston
Attorney Docket Number	2183-5223US

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		ABRAHAM, E., "Coagulation Abnormalities in Acute Lung Injury and Sepsis," Am. J. Respir. Cell Mol. Biol., 2000, pp. 401-404, Vol. 22.	
		ADIB-CONQUY et al., "NF-kappaB Expression in Mononuclear Cells in Patients with Sepsis Resembles That Observed in Lipopolysaccharide Tolerance," Am. J. Respir. Crit. Care Med., 2000, pp. 1877-1883, Vol. 162.	
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		BROWN et al., "Two Forms of NF-kappaB1 (p105/p50) in Murine Macrophages: Differential Regulation by Lipopolysaccharide, Interleukin-2, and Interferon-gamma," Journal of Interferon and Cytokine Research, 1997, pp. 295-306, Vol. 17.	
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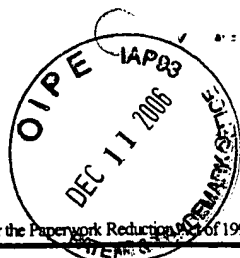
Examiner  
SignatureDate  
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08A (10-01)



PTO/SB/08B(10-03)

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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 2 of 2

**Complete if Known**

Application Number	10/028,075
Filing Date	December 21, 2001
First Named Inventor	Khan et al.
Group Art Unit	1636
Examiner Name	J. Dunston
Attorney Docket Number	2183-52231JS

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		CUI et al., Am. J. Physiol. Integr. Comp. Physiol., 2004, pp. R699-R709, Vol. 286.	
		DWINNELL et al., Atlas of Diseases of the Kidney, Blackwell Sciences, 1999, pp. 12.1-12.12, Ch. 12.	
		KALNS et al., Biochem. Biophys. Res. Comm., 2002, pp. 506-09, Vol. 297.	
		KALNS et al., Biochem. Biophys. Res. Comm., 2002, pp. 41-44, Vol. 292.	
		Merck Index, 17th ed. 1999, pp. 1145-1146, 1841-1848, 2539, 2551.	
		Merriam-Webster Medical Dictionary, 1994, p. 82.	
		MOAYERI et al., Journal of Clinical Investigation, September 2003, pp. 670-82, Vol. 112, No. 5.	
		NGO et al., The protein folding problem and tertiary structure prediction, 1994, pp. 492-94.	
		PELLIZZARI et al., FEBS Letters, 1999, pp. 199-204, Vol. 462.	

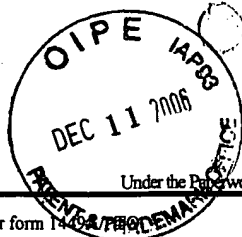
Examiner  
SignatureDate  
Considered

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet

1

of

2

**Complete if Known**

Application Number	10/028,075
Filing Date	December 21, 2001
First Named Inventor	Khan et. al.
Group Art Unit	1632
Examiner Name	T. McKelvey
Attorney Docket Number	2183-5223US

**U.S. PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
		US- 4,977,244	12-11-1990	Muchmore et al.	
		US- 5,677,275	10-14-1997	Lunardi-Iskandar et al.	
		US- 5,877,148	03-02-1999	Lunardi-Iskandar et al.	
		US- 5,958,413	09-28-1999	Anagnostopoulos et al.	
		US- 5,997,871	12-07-1999	Gallo et al.	
		US- 6,319,504 B1	11-20-2001	Gallo et al.	
		US- 2003/0049273 A1	03-13-2003	Gallo et al.	
		US- 6,583,109 B1	06-24-2003	Gallo et al.	
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		US- 6,620,416 B1	09-16-2003	Gallo et al.	
		US- 2002/0064501	05-30-2002	Khan et al.	
		US- 2002/0041871	04-11-2002	Brudnak	
		US- 5,851,997	12-22-1998	Harris	
		US- 6,489,296	12-03-2002	Grinnell et al.	

**FOREIGN PATENT DOCUMENTS**

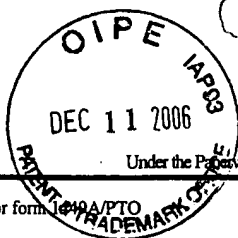
Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
		EP 1 300 418	04-09-2003	Erasmus Universiteit Rotterdam		
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		WO 02/085117	10-31-2002	Eisai Co., Ltd.		
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		DE 19953339	05-17-2001	Goldham Pharma GmbH		
		96/04008	02-15-1996	Government of the United States		
		97/49373	12-31-1997	University of Maryland Biotechnology Institute		
		97/49418	12-31-1997	University of Maryland Biotechnology Institute		
		97/49432	12-31-1997	University of Maryland Biotechnology Institute		

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2

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2

**Complete if Known**

Application Number	10/028,075
Filing Date	December 21, 2001
First Named Inventor	Khan et. al.
Group Art Unit	1632
Examiner Name	T. McKelvey
Attorney Docket Number	2183-5223US

**OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS**

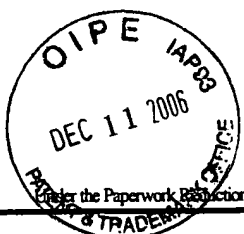
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Sheet 3 of 3

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Application Number	10/028,075
Filing Date	December 21, 2001
First Named Inventor	Khan et al.
Group Art Unit	1636
Examiner Name	J. Dunston
Attorney Docket Number	2183-5223UIS

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
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Application Number	10/028,075
Filing Date	12/21/2001
First Named Inventor	Khan et al.
Group Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	2183-5223US

### OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

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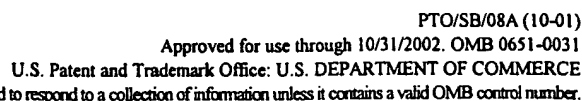
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Sheet	1	of	2
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Application Number	10/028,075
Filing Date	December 21, 2001
First Named Inventor	Khan et al.
Group Art Unit	1636
Examiner Name	T. McKelvey
Attorney Docket Number	2183-5223US

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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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Application Number	10/028,075
Filing Date	December 21, 2001
First Named Inventor	Khan et al.
Group Art Unit	1636
Examiner Name	T. McKelvey
Attorney Docket Number	2183-5223US

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Sheet

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**Complete if Known**

Application Number

10/028,075

Filing Date

December 21, 2001

First Named Inventor

Khan et al.

**Group Art Unit**

To be assigned

**Examiner Name**

To be assigned

Attorney Docket Number

2183-5223US

## U.S. PATENT DOCUMENTS

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Application Number	10/028,075
Filing Date	December 21, 2001
First Named Inventor	Khan et al.
Group Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	2183-5223US

**OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS**

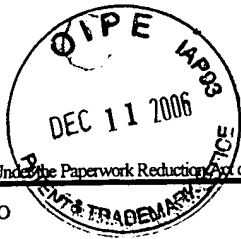
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		PCT International Search Report, PCT/NL01/00259, dated December 18, 2001, 3 pages.	
		PCT International Preliminary Examination Report, PCT/NL99/00313, dated July 21, 2000, 6 pages.	
		PCT International Search Report, PCT/EP99/00313, dated November 29, 1999, 3 pages.	
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		Iskandar et al., "Effects of a urinary factor from women in early pregnancy on HIV-1. SIV and associated disease", <u>Nature Medicine</u> , April 1998, Vol. 4, No. 4, pp. 428-434.	

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Sheet 1 of 1

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Application Number	10/028,075
Filing Date	December 21, 2001
First Named Inventor	Khan et al.
Group Art Unit	1636
Examiner Name	T. McKelvey
Attorney Docket Number	2183-5223US

**U.S. PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
		US-5,380,668	01-10-1995	Herron	
		US- 2003/0186244 A1	10-02-2003	Margus et al.	
		US- 2003/0113733 A1	06-19-2003	Khan et al.	
		US- 2003/0119720 A1	06-26-2003	Khan et al.	
		US- 2002/0064501 A1	05-30-2002	Khan et al.	
		US- 2003/0166556 A1	09-04-2003	Khan et al.	
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		US- 2003/0220257 A1	11-27-2003	Benner et al.	
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**FOREIGN PATENT DOCUMENTS**

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